

**Delaware Health Resources Board  
Christiana Care Health System Structural Lab Review Committee Meeting  
Tuesday, October 24, 2017 10:00 AM  
Thomas Collins Building  
540 South Dupont Highway Dover, DE 19901  
DDDS First Floor Conference Room 106**

***Review Committee Members Present:***

Carolyn Morris Chair, Lynn Fahey and Vincent Lobo D.O.

***Staff Present:***

Jennifer Singh and Latoya Wright.

***Call to Order and Welcome***

The meeting of the Review Committee for Christiana Care Health System (Christiana Care) was called to order at 10:15 a.m.

***Review of Christiana Care LLC Application***

The Review Committee reviewed the application along with the Internal Staff Analysis document.

It was stated that on May 12, 2017, Christiana Care submitted a Notice of Intent to construct a structural heart interventional lab (the lab). The application was received on July 28, 2017 with an estimated capital expenditure of approximately \$3.5 million. The public notice was posted on August 24, 2017. There was no request for a public hearing which makes the review period 90 days from the date of the public notice.

***Project Summary and Background Information***

Christiana Care proposes to add a new laboratory for procedures at Christiana Hospital with hybrid capabilities to modernize and improve the cardiovascular patient experience. The new laboratory will enable them to treat cardiovascular diseases, provide innovative care and improve health outcomes for their aging, complex patient population. Christiana states there is an increasing incidence of cardiovascular disease in an aging population who can have high rates of mortality and morbidity from traditional open surgeries. Structural heart disease interventions and minimally invasive cardiovascular surgery procedures are transforming health care delivery through a combination of advanced technologies and catheter-based surgical techniques targeted for the high-risk patient population.

The core offering of a structural heart disease program is Transcatheter Aortic Valve Replacement (TAVR) and in FY 2016, Christiana Care's TAVR volumes grew 72% from the prior fiscal year. In August 2016, TAVR was approved by the FDA for use in intermediate-risk patients. According to market insights from The Advisory Board, indication expansion to intermediate-risk patients is poised to drastically grow the market size. There are many patients who may now be new candidates for TAVR. Clinical trial data published shows TAVR in

intermediate-risk patients has low complication rates, superior blood flow performance, and lower rates of stroke and mortality compared to open surgery (*The Advisory Board, How to Optimize TAVR and Valve Programs, August 2016*). Christiana Care states that the Centers for Medicare and Medicaid Services also expanded their reimbursement criteria to moderate risk patients, which is contributing to procedure growth. Christiana Care's current operating room (OR) space is not ideally suited for performing these complex structural heart disease procedures. The OR lacks the most technologically advanced 3D imaging systems, and is already highly utilized, causing delays and impacting patient experience.

It was stated this initiative has the potential to significantly change the way care is delivered over the next several years. It opens the door to a one-stop treatment approach where a specialized heart team has access to the necessary tools and advanced imaging capabilities they need in one place to execute complex procedures. This eliminates the need for multiple procedures and prolonged hospital stays. To the patient, the procedure experience will be simpler and more convenient. The procedures eliminate sternotomy, long recoveries in the hospital and at home, and reduce pain. To providers, the procedures offer new options to more patients who previously may have been at high risk or simply apprehensive for surgery.

The lab will be constructed on the second floor of Christiana Hospital using existing shell space within the Center for Heart and Vascular Health. The project includes renovation of the existing facility and equipment purchase with an estimated capital expenditure of \$3,500,000.

It was noted, in addition to the Advisory Board, reference resources contributing to the foundation of this project include the Journal of the American College of Cardiology, *Structural Heart Disease Interventions* (Carroll and Webb, 2012), and the American Heart Association's overview of *Planning, Building and Using the Cardiac Surgical Hybrid OR*, (Dr. Hersh Maniar, Division of Cardiothoracic Surgery, 2014).

### ***Review Considerations***

The Review Committee reviewed the following criteria for the proposal to determine whether the application meets or does not meet each criterion.

Criterion I: The relationship of the proposal to the Health Resources Management Plan (HRMP)  
The seven guiding principles were discussed as it relates to the HRMP.

**Principle 1: Applications should demonstrate consideration of access, cost, and quality of care issues:** The proposed project will increase access to TAVR and a handful of new, hybrid cardiovascular procedures that are becoming common across the health care industry (see Schedule 3). The evolution of care from an invasive open-chest procedure to a minimally invasive catheter-based procedure will help them serve a larger number of patients and will reduce the total cost of care through improved efficiency, a reduction in inpatient stay days, and an expedited recovery for the patient.

**Principle 2: Applicants are expected to contribute to the care of the medically indigent:**

Christiana Care provides services regardless of ability to pay and provided in excess of \$10.6 million in indigent care in FY16.

**Principle 3: Projects should support a managed, coordinated approach to service healthcare needs:** Cardiac surgeons, interventional cardiologists, surgical nursing staff, anesthesiologists and diagnostic imagers will work together in the proposed laboratory to perform image-guided, surgical procedures in real time. The combined space will be more efficient because it will replace multiple visits for the patient and improve coordination among highly skilled staff.

**Principle 4: Availability of out-of-state resources:** Structural heart labs are available in adjacent states. In fact, they are becoming a common piece of many health systems' cardiovascular programs. Most recent Mercy Fitzgerald Hospital, a member of the Trinity Health System, publicized the opening of their structural heart program in Delaware County in their constituent newsletter and available online here <http://www.mercyhealth.org/resources/newsletter/mercy-fitzgerald/minimally-invasive-heart-surgery/>.

**Principle 5: Discourage incentives for over-utilization: Not applicable:** Surgeons at Christiana Care are performing minimally invasive heart procedures currently. The investment represented by this application is positioned to enhance efficiency and throughput for procedures that are in demand among the aging population. The intent of the health system is not to promote overutilization of procedures beyond the relevant population, but to provide an optimal setting for both the patient and surgical team. Growth in volume will be a result of natural population growth, especially within the older adult age cohort, and the expansion of indication for use in intermediate risk patients that was provided by the FDA in 2016.

**Principle 6: Projects enhancing meaningful markets are to be encouraged:** Structural heart issues are common in the aging population. As the Baby Boomer generation ages, the health system is seeking ways to more efficiently and effectively serve a larger proportion of older patients. The procedures performed in the lab provide the patient with a better chance of achieving optimal health, which may translate into fewer years of disability and dependency and a better chance of preventing or forestalling the need for institutionalized skilled nursing care.

**Principle 7: Projects improving the health status of Delawareans are essential:** The minimally invasive nature of the procedures to be performed in this space will allow Christiana to serve existing patients and offer lifesaving procedures to patients who in the past have been considered too medically fragile to undergo an open procedure. The ability to fix problems related to the structure of the heart is well within reach and now a larger proportion of the older adult population can receive these procedures so that they have a better quality of life. A permanent fix to a structural heart issue improves the patient's overall health and well-being.

The Review Committee discussed the advantages of providing cardiovascular procedures that are less invasive as opposed to open chest procedures and the reduction in stays for the patient.

The Review Committee agreed the application meets criterion I.





**Criterion II: The need of the population for the proposed project**

The application noted there is an increasing incidence of cardiovascular disease in an aging population who can have high rates of mortality and morbidity from traditional open surgeries. The market for minimally invasive options that offer the same quality and outcomes to surgery is expected to grow rapidly arising from increased consumer demand and further technology advances making the intervention available to more patients. In August 2016, TAVR was approved by the FDA for use in intermediate-risk patients. Christiana Care expects significant TAVR growth with indication expansion to intermediate-risk. Clinical trial data show TAVR in intermediate-risk patients has low complication rates, superior blood flow performance, and lower rates of stroke and mortality compared to open surgery (*The Advisory Board*).

The Review Committee discussed the Advisory Board mentioned in the application. They submitted a follow up question inquiring about the Advisory Board and if the Board was an outside source or an internal source.

The inpatient cardiac market for Delaware, which includes cardiac catheterization, cardiac electrophysiology (EP), medical cardiology and cardiac surgery, is expected to decline over time as services shift to outpatient sites of care. In cardiac surgery, a percentage of the decline will be attributed to surgical valve case mix shifting to structural heart interventions. TAVR and endovascular valve volumes (DRG 266 and 267) are expected to soar over the same period of time. The application provided cardiovascular market estimations.

**State of Delaware - Cardiovascular Market Estimations**

	<b>5 Year Growth</b>	<b>10 Year Growth</b>
Inpatient Cardiac Services - Catheterization, Electrophysiology, Medical Cardiology, & Cardiovascular Surgery	 -10.1%	-8.2%
Outpatient Cardiac Services	 11.4%	22.9%
Cardiac Surgery	 -4.6%	-3.9%
Endovascular Cardiac Valve Replacement	 69.3%	121.3%

Source: The Advisory Board market estimators were used to assess Christiana Care's local cardiovascular market growth.

**Service Area and Demographics**

Christiana Care's primary service area, based on patient origin analysis, is New Castle County, Delaware. Information noted in the application asserts to the population growth in New Castle DE over the new few years.

The Delaware Population Projections according to the Delaware Population Consortium were also discussed. It was noted that over the years, New Castle County is expected to grow 11.6%.

The Review Committed stated they will vote that the application meets criterion II contingent upon the question proposed to Christiana Care references the Advisory Board. Staff will provide Christiana's Care response from the applicant.

The Review Committee agreed the application meets criterion II.

Criterion III: The availability of less costly and/or more effective alternatives to the proposal, including alternatives involving the use of resources located outside the state of Delaware. Alternative providers for this procedure are located outside of the state. Cardiovascular programs that offer the TAVR procedure generally have a specialized lab like the one described in the application. These include the University of Pennsylvania Health System, Inspira Health Network, Main Line Health and others in the larger region.

There was a discussion surrounding the complexity of performing open surgeries as it may relate to morbidity and the benefits of the proposed laboratory.

The Review Committee agreed the application meets criterion III.

Criterion IV: The relationship of the proposal to the existing health care delivery system. Christiana Care is a regional provider that serves the full spectrum of patient needs ranging from trauma and emergency care to traditional inpatient care, routine and preventive health services. Unlike some other surgical procedures, such as those related to total joint replacement and general surgery, heart procedures are high risk and typically not performed in a free-standing surgery center. Cardiac patients may, at any time, require acute life-saving intervention that only a tertiary care facility such as Christiana Hospital could provide.

### **Referral Arrangements**

Christiana Hospital provides the highest level of care within this service category; no referral arrangements are necessary beyond their established discharge planning process where they ensure that the patient receives appropriate medical and home-based follow-up care.

The Review Committee agreed the application meets criterion IV.

Criterion V: The immediate and long-term viability of the proposal in terms of the applicant's access to financial, management and other necessary resources.

### **Health Manpower**

Christiana Care continually strives to be a great place to work by appealing to a diverse employee population, offering competitive pay and flexible scheduling options for Work Life Balance programs. Christiana has 11,308 employees and 1,379 volunteers that contributed 78,901 volunteer hours. With turnover and vacancy rates lower than the national average, and an average length of service of 11 years, Christiana Care has been able to attract and retain the healthcare manpower needed.

Schedule 7, ‘Changes in Staffing,’ illustrates the impact upon staffing by personnel category for the first year of operation following completion of the project. This proposal includes the addition of two FTEs.

### **Available Capital**

The lab at Christiana Hospital will require an investment of \$3.5 million. The project will be funded in its entirety with cash. The majority of the cost will go toward renovation (\$1.5 million) and equipment (\$1.97 million). Christiana Care Health System maintains an AA Bond rating and the use of operating cash to fund the project will not affect this rating.

The Review Committee discussed Schedule 7 in the application. There was a discussion surrounding the staff. The Review Committee submitted a follow up question to Christiana Care inquiring if there will be a need for additional surgeons for the new lab or will the existing surgeons be utilized.

The Review Committee agreed the application meets criterion V.

Criterion VI: The anticipated effect of the proposal on the costs of and charges for health care.  
In the first full year of operation, the project will increase Christiana Care Health Services operating revenues and expenses by \$1,044,312 and \$1,547,946 respectively.

The projected first year operating revenue reflects the increased patient volume for the services, current governmental reimbursement, and existing contracts with private payers, and continued provisions of uncompensated care. The following provides detail related to the impact upon expenses for the first year of operation:

Salaries and Wages	\$143,062
Fringe Benefits	\$43,977
Supplies	\$71,304
Services	\$161,232
Depreciation	\$319,886
Ancillary	\$808,486
Total	\$1,547,947

- Salary, wages, and fringe benefits are reflective of the patient care and support services staff necessary to accommodate the increase in related services. Please refer to Schedule 7, “Changes in Staffing,” for complete details.
- Supplies and other expenses are significantly related to increases in medical supplies, purchased services, and facility costs necessary to support the additional patient services.

- The depreciation expense is derived from the equipment and construction outlays related to the project.

Schedule 4 in the application, the Statement of Revenue was discussed. There was a discussion regarding the costs associated with open chest surgeries and less invasive surgeries. It was mentioned that it is expected that the new proposed laboratory would be more cost effective.

The Review Committee agreed the application meets criterion VI.

Criterion VII: The anticipated effect of the proposal on the quality of health care.

Christiana Care is certified by Medicare and Medicaid. Christiana Care is also accredited by the Joint Commission on Accreditation of Healthcare Organizations. Christiana Care notes in the application the services the project will offer support value based care delivery and improve the patient experience and provide clinical outcomes.

The Review Committee agreed the application meets criterion VII.

#### ***Next Steps***

The Board will vote on the application at the November 16, 2017 Health Resources Board meeting.

#### ***Adjourn***

The meeting adjourned at 11:07 a.m.

#### ***Guests Attending***

Leslie Mulshenock

Lisa Lednum

Christiana Care

Christiana Care